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FRIDAY, APRIL 8, 1977

PART VIII

CONSUMER PRODUCT SAFETY COMMISSION

■

CHILDREN'S WEARING APPAREL CONTAINING TRIS

Interpretation as Banned Hazardous Substance

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

Children's Wearing Apparel Containing TRIS; Interpretation as Banned Hazardous Substance

AGENCY: Consumer Product Safety Commission.

ACTION: Interpretation of a statutory provision.

SUMMARY: The Commission is notifying the public that children's clothing containing the chemical flame-retardant TRIS is banned from commerce. According to the applicable statutory provisions, such clothing is banned by definition because it is intended for use by children and could cause substantial illness because of its toxicity.

Tests have established that TRIS causes cancer in animals, and can enter the bodies of children by being absorbed through the skin. This absorption occurs when children wear TRIS-treated clothing. Children also ingest TRIS by "mouthing" the clothing.

Since washing removes much of the available TRIS, children's clothing containing TRIS that is already in the hands of consumers, unless unwashed, is not banned. However, children's clothing containing TRIS that is in commerce on April 8, 1977, or is introduced into commerce after that date is banned and must be repurchased by any manufacturers or others who sold it.

DATES: The interpretation is effective on April 8, 1977.

FOR FURTHER INFORMATION CONTACT:

Francine Shacter, Office of Standards Coordination and Appraisal, Consumer Product Safety Commission, Washington, D.C. 20207. (202–492–6470).

ADDRESS: All of the documents, studies, and other materials that are discussed in the preamble and listed under References are available from the Office of the Secretary, 1111 18th Street NW., Washington, D.C. 20207. (202–634–7700).

SUPPLEMENTAL INFORMATION:

Background

In March 1976 the Environmental Defense Fund (EDF), a health-oriented public interest organization, petitioned the Commission to require cautionary labeling for wearing apparel containing the chemical flame-retardant TRIS (2,3-dibromopropyl) phosphate, hereafter "TRIS," in surface concentrations in excess of 100 parts per million (ppm). This petition (HP 76–10) was based on data that showed that TRIS was capable of inducing mutations in Salmonella typhimurium when tested in both the presence and absence of metabolic activating systems (1,2,3)[1] The petition asserted at page 10 that this test has been shown to be a "highly reliable predictor" of carcinogenicity.

[1] The documents cited by parenthetical numbers correspond to the documents listed in the section on References, below.

The Commission conducted a search of the existing literature in April 1976, and initiated a biological testing program in its own laboratories in June 1976 to evaluate the scientific issues raised in the petition. In addition, the Commission asked the National Cancer Institute (NCI) to expedite its rat and mouse carcinogenicity feeding studies involving TRIS that were already underway (*4*). The NCI agreed to provide the Commission with preliminary results from these studies as they became available (*5*).

On February 4, 1977 the Commission obtained the preliminary NCI test data (*6*). Within two weeks, the Commission's Bureau of Biomedical Science (BBS) provided a statistical analysis of the NCI rat and mouse bioassay study. (*7*).

Based on its analysis of the same NCI preliminary test results, EDF petitioned the Commission on February 8, 1977 (HP 77–8) to ban the sale of wearing apparel containing TRIS (*8*). The Commission's technical staff met with Dr. Robert Harris, Dr. Joseph Highland, and Mr. Robert Rauch of EDF on February 18 to discuss this petition.

On March 2, the Commission met with Dr. Marvin Schneiderman, an Associate Director of the National Cancer Institute, and on March 8 the Commission met with the same EDF representatives that had met with the staff. All of these meetings were open to the public and transcripts are available (*9, 10, 11*).

Ms. Joanne Siegel and Dr. Reuben Epstein also petitioned the Commission, on February 1, 1977, to address the risk presented by wearing apparel containing TRIS (*12*). This petition (FP 77–1) requests the Commission to amend or revoke its flammability standard for children's sleepwear sizes 0–6X (16 CFR Part 1615), issued under the Flammable Fabrics Act, which has encouraged the use by manufacturers of TRIS as a flame retardant (although this standard imposes performance requirements concerning flame resistance, it neither prohibits nor requires the use of TRIS or any other chemical flame retardant).

On March 16, 1977 an updated draft of the TRIS bioassay results was released by NCI for the March 25 meetings of the Data Evaluation and Risk Assessment Subgroups of the Clearinghouse on Environmental Carcinogens (*13*). These two subgroups act as statutory advisory groups to the NCI's Division of Cancer Cause and Prevention. At its March 25 meeting, the Data Evaluation Subgroup reviewed and approved the NCI bioassay results for TRIS (*14*).

Early in April 1977, the Commission completed its final report (*15*) on its subchronic dermal and oral ingestion studies along with radioactive ^{14}C-TRIS tracer studies and human lifetime risk estimates of cancer in the human population. These will be discussed in more detail in the section of Hazard, below.

Hazard

A. CARCINOGENICITY

The Commission has carefully reviewed the preliminary data from the National Cancer Institute on the carcinogenicity of TRIS (*6*). Under the NCI testing program, begun early in 1974, rats and mice were fed TRIS daily at two dose levels. Weanling animals of both sexes were placed on diets containing 50 (low dose) or 100 (high dose) ppm TRIS in the case of rats; 500 (low dose) or 1,000 (high dose) ppm TRIS in the case of mice; or no TRIS (control animals). After two years the surviving animals were sacrificed and examined for pathological changes.

The test mice that were fed TRIS developed tumors in the liver, the kidney, the lung and the stomach and the test rats developed tumors in the kidneys (preliminary Table II in (*6*)). These test data establish TRIS as an animal carcinogen in two species and at multiple sites.

The Commission has no conclusive data that establish that TRIS has caused cancer in humans. Since cancers develop over many years and cannot be easily linked to particular causes, this is not unexpected. The Commission's Office of the Medical Director (OMD) believes that once a substance is established as an animal carcinogen it can never be assured as a safe substance for human exposure (*16*). In addition, OMD believes that all known human carcinogens have been shown to be carcinogenic in laboratory animals (*16, 17*).

Dr. Marvin Schneiderman of NCI has told the Commission that he knows of no chemicals that provide a high risk to animals but no risk to humans (pp. 43–44 of (*10*)). The February 1977 EDF petition asserts that TRIS is as potent or more potent in animals than a number of known human carcinogens (pp. 13–13a of (*8*)). Research Associate N. Kim Hooper and Professor Bruce N. Ames of the University of California, Berkeley's Department of Biochemistry, have stated in a March 21, 1977 letter to Chairman Byington (*18*) that TRIS is a more potent carcinogen than the human carcinogen benzidine or β-naphthylamine (p. 3 of (*18*)).

In a June 2, 1976 report, (*19*), the National Cancer Advisory Board states "A major source of data on carcinogenicity comes from bioassays in experimental animals. Experience has indicated that, with one or two possible exceptions, compounds that are carcinogenic in humans are also carcinogenic in one or more experimental animal bioassay systems. In addition, several compounds first detected as carcinogens in experimental animals were later found to cause human cancer. Demonstration that a compound is carcinogenic in animals should, therefore, be considered evidence that it is likely to be carcinogenic in humans, unless there is strong evidence in humans to the contrary." (See also p. 11 of (*8*).)

B. MUTAGENICITY

The Commission has received several reports on the mutagenic potential of TRIS. Hooper and Ames (pp. 1 and 3 of (*18*)) focus on bacterial systems utilizing various grades of TRIS and TRIS-treated cloth. They also point out that

TRIS is a potent mutagen in Drosophila, causing large numbers of recessive lethal mutations in offspring. Moreover, they assert that TRIS is capable of causing damage to DNA synthesis in human cells in tissue culture.

The general assertion of Hooper and Ames is that TRIS is mutagenic and "likely to cause genetic birth defects in the offspring of children exposed to it" (p. 1 of (*18*)). They base this conclusion on their belief that TRIS can be absorbed through the scrotum and could effect spermatogenesis.

Dr. M. Prival, in an article entitled, "Tris (2,3-Dibromopropyl) Phosphate: Mutagenicity of a Widely Used Flame Retardant" (*20*), has found TRIS to be mutagenic in histidine-requiring strains of Salmonella typhimurium (although he does not believe his results conclusively demonstrate that TRIS is a carcinogen).

It must be noted that the BBS analysis of bone marrow chromosomes obtained from rats which received either a single or multiple daily oral dose of TRIS five days per week for 13 weeks did not demonstrate any chromosome aberrations (*15*).

C. EXPOSURE

TRIS is incorporated into some wearing apparel in at least two ways, according to information obtained by the Commission's Bureau of Engineering Sciences (*21*). Certain wearing apparel is manufactured from fabric knitted or woven from fibers that contain TRIS. Other apparel is manufactured from fabric that has been topically treated with TRIS. In both cases, some TRIS that is not tightly bound or contained within the fibers can be removed from the garment by the sucking, or "mouthing," of an infant on the sleeve or other portion of the garment. The TRIS that infants can ingest in this manner is a source of exposure of infants to TRIS. Another source of exposure is absorption through the skin.

The Commission has reviewed various estimates of the amount of TRIS to which a child may be exposed. These estimates come from a March 16, 1977, report prepared by the Bureau of Biomedical Science (*22*); from a March 8, 1977 report by Robert H. Harris, Ph. D., of EDF, entitled Estimating the Cancer Hazard to Children From Tris-treated Sleepwear (*23*); and from the March 21 Hooper and Ames letter (*18*). The general assumptions underlying all of these estimates are (a) that a child mouths the garment and ingests available TRIS; (b) that there is absorption through the skin; and (c) that the child wears numerous garments over a period of time containing various amounts of available TRIS.

(1) *Bureau of Biomedical Science.* BBS has prepared a range of estimates on the amount of TRIS to which a child could be exposed over a 6-year period, both from skin absorption and from mouthing. Their estimates of total TRIS absorbed ranged from 2.5 to 77.4 mg/kg, depending upon the body area exposed to TRIS-treated garments.

In the Commission's subchronic toxicity and dermal penetration studies, the groups of rats which received daily doses of TRIS by the oral route (25 mg/kg and 250 mg/kg) demonstrated renal nephrosis following a 13 week period. The weekly dermal application of 1 ml/kg of undiluted TRIS to clipped rabbits produced renal nephrosis and testicular atrophy also at the end of a 13 week period. This data correlates well with NCI's finding of renal carcinoma in rats and mice at a 2-year period.

The degree of penetration of TRIS in rabbit and rat of both sexes was determined following dermal application of ^{14}C-TRIS at 0.9 ml/kg and at 0.05 ml/kg. Radiolabeled TRIS from TRIS-treated cloth was also shown to penetrate the skins of rabbits. Penetration was enhanced by the presence of urine on the cloth. The kidney was found to be the organ of highest specific radioactivity in all cases. Most of the absorbed radiolabeled TRIS was excreted in the urine (for more detail see (*15*)).

(2) *Environmental Defense Fund.* EDF estimates of the total lifetime exposure for a child range between .085 mg/kg to 85 mg/kg (p. 15 of (*23*)) and are based primarily upon dermal absorption for a 10 or 20 kg child exposed to one, ten or 20 pairs of TRIS treated sleepwear.

(3) *Hooper and Ames.* Based on one year of exposure of a 7 kg child, Ames and Hooper estimate that the exposure due to dermal absorption would be 70 mg/kg/year and the dose a child receives by sucking is estimated as one percent of that obtained through skin absorption (*18*).

D. RISK ASSESSMENT

The Commission has considered risk assessments that are based on the estimates of exposure cited in Section C, above. The methods used to prepare the estimates are described in a March 1977 paper entitled, Estimates of Human Lifetime Carcinogenic Risk From Exposure to TRIS, prepared by Drs. Charles Brown, Marvin Schneiderman, and Kenneth Chu of the National Cancer Institute (*24*). The statistical extrapolations are based on the use of two mathematical models: The single-hit model (linear no threshold) and the log-probit model (Mantel-Bryan). The use of these mathematical models and the extrapolations from animals to man rest on the following assumptions: (a) the animal dose can be converted to an "equivalent" human exposure level; (b) mouse and man, and rat and man, have equal sensitivities to TRIS; (c) infants and chlidren are no more, or less, sensitive to TRIS than are adults; and (d) the dose given to an animal during its entire life can be converted to an equivalent daily dose during a specific period of time which is less than a lifetime.

(1) *Bureau of Biomedical Science.* BBS has projected cancer incidence rates based on its exposure estimates and on data from the NCI study. These projected rates show the kidney to be the primary target organ. The best estimates of BBS (*25*) is approximately 300 kidney cancers per million male population. For females the projected rate is about one-fifth that of males.

Based on the single hit model the BBS estimates for lifetime risk of cancer of the kidney is between 60 and 1,800 cases per million male population. For the log probit model the estimates range from 25 to 5,100 cases per million males. All of these estimates are lifetime risk or lifetime incidence estimates.

(2) *Environmental Defense Fund.* EDF also provided its estimates on human exposure to NCI which used the same models, and these data provided estimates of a lifetime incidence of cancer of as high as 6,000 per million male population, based on maximum exposure, the rat kidney and the log probit model.

(3) *Hooper and Ames.* Hooper and Ames estimate that for one year of exposure, 1.7 percent of the children would develop cancer (17,000 cases/million). An exposure throughout childhood would give a higher risk (p. 8 of (*18*)).

E. EFFECT OF WASHING

There is evidence both from the March 1976 EDF petition (*1*) and from reports of the Commission's Bureau of Engineering Sciences (*21*) that the amount of TRIS that can be easily removed from a garment is appreciably reduced by repeated washings. The March 1976 petition states at page 5 that "* * * most of the surface TRIS could be washed out of the fabrics, which implies that laundering in use will reduce exposure to TRIS. For example, two samples of different polyester fabric had 70,000 ppm and 37,500 ppm of surface TRIS before, and 35 ppm and 100 ppm of surface TRIS after washing, respectively. It would appear from these studies that during the first three washings of polyester fabrics, surface TRIS can be reduced by greater than 95%, while the total amount in the fabric will be reduced by only about 12%." (The fabric containing 70,000 ppm had been specifically treated for test purposes and has not been commercially marketed.)

According to the BBS review of literature data, acetate fabrics contain 65–600 ppm "surface TRIS" [2] (more uniform and lower concentrations than polyester) and polyester fabrics contain 260–37,500 ppm surface TRIS. Although BES stresses the limited reliability of these figures, estimates from the studies show that washing removes up to 85 percent of surface concentration in acetate fabrics and from 21 to 82 percent in polyester fabrics.

F. EFFECT ON FLAMMABILITY INJURIES

Much of the use of TRIS in wearing apparel is to meet the Commission's flammability standards for children's sleepwear (16 CFR Parts 1615 and 1616). The Commission's Bureau of Epidemiology (BEP) believes, based on an analysis of injury information and on an article on children treated by physicians,

[2] The term "surface TRIS" is merely one of convenience. Whether or not the easily removable TRIS is literally on the surface of the fibers is unknown. The more fundamental distinction would appear to be between that amount of TRIS that is loosely bound to fibers and that which is more tightly bound, wherever it may be.

that children who are burned while wearing flame-resistant sleepwear tend to sustain less extensive burns than children who are burned while wearing non-flame-resistant sleepwear (*26*). Data indicate that the number of deaths to children ages 1–4 due to clothing ignition decreased following the effective date of the standard for children's sleepwear in sizes 0–6X.

Because the Commission's flammability standards for children's sleepwear are performance standards, the Commission assumes that manufacturers can and will comply with the standard without using TRIS or any other chemical which presents a hazard to the consumer. There are fabrics which meet the standard without using any chemical flame retardants (*27*).

Marketing Factors

Garments treated with TRIS are made of either 100 percent polyester or acetate and triacetate blends. There is no certain way to distinguish among 100 percent polyester fabrics that are untreated, treated with TRIS, or treated with another flame retardant. The Commission understands, however, that all acetate and triacetate fibers used in children's sleepwear fabrics contain TRIS.

The Commission has found that flame resistant garments currently on the market are: (a) children's sleepwear, sizes 0–14, for which the flame resistant requirement is mandatory, and (b) those which resulted from voluntary programs undertaken by a few major retailers. The Commission believes that there is no significant inventory of flame-resistant garments resulting from voluntary program at this time (p. 4 of (*27*)).

The Commission's Bureau of Economic Analysis (BEA), in a March 21, 1977 report (*28*) has estimated that 18 million garments, over one-third of the spring 1977 production of children's sleepwear, contain TRIS. If inventories are taken into account, the portion of TRIS-treated merchandise would be over 40% of all children's sleepwear in the retail pipeline, or about 20 million garments. About 10–20 percent of this has already been sold to consumers. In addition, BEA has estimated that about 7 million square yards of TRIS-treated fabric is in inventory with fabric and garment producers.

BEA believes that a small number of national retail chain outlets and very large discount stores account for more than 55 percent of children's sleepwear sales, while department stores account for 20 percent, and specialty and variety stores account for less than 10 percent of annual sales.

Environmental Impact

The Commission has considered the potential enviromnental impacts of its interpretation that TRIS-treated wearing apparel is a banned hazardous substance. A preliminary environmental assessment is available (*29*) and a final assessment will be available as soon as possible. The Commission has investigated anticipated impacts relating to chemical flame-retardants that will be used as substitutes for TRIS, relating to substitute end-use products, and relating to the disposal of garments, fabrics, fibers, or yarns treated with TRIS, as well as the anticipated economic impacts.

Based on the information that is available thus far, it appears that there will be no significant effect on the human environment resulting for disposal of TRIS-treated garments, fabrics, fibers, or yarns. While more information is needed on the potential impacts from the use of substitute chemical flame-retardants and substitute end-use products, the Commission knows of no significant effects in this area at this time.

Because of the emergency circumstances of the ban on TRIS-treated children's wearing apparel, the Commission has been in contact with the Council on Environmental Quality (CEQ) concerning alternative arrangements for complying with the CEQ guidelines on the National Environmental Policy Act (*30*). As of this date, the Commission's staff has received oral CEQ concurrence with this approach.

References

The parenthetical numbers used in the above portion of the preamble refer to the following documents, studies, and other materials:

(*1*) March 24, 1976 petition (HP 76–10) from the Environmental Defense Fund.

(*2*) Letter from Glenn E. Schweitzer, Director, Office of Toxic Substances, EPA to Stanley R. Parent, Executive Director, CPSC, October 21, 1976, and a similar letter to Dr. David Rall, Director, NIEHS, on the same date.

(*3*) Ames, B., in a letter to Dr. B. L. Van Duuren, New York University Medical Center, January 28, 1976.

(*4*) November 8, 1976 letter from Chairman S. John Byington to Frank J. Rauscher, Ph. D., Director of the National Cancer Program of NIH.

(*5*) December 3, 1976 letter from Robert A. Squire, D.V.M., Ph. D., Acting Chief of the Carcinogen Bioassay and Program Resources Branch at NIH, to Chairman Byington.

(*6*) Preliminary NCI data on TRIS bioassay feeding studies.

(*7*) Memo from R. M. Hehir to Don Clay on February 16, 1977 entitled "BBS Statistical Analysis of NCI Cancer Bioassay Report on TRIS (2,3-dibromopropyl) phosphate, with attachments.

(*8*) February 8, 1977 petition (HP 77–8) from the Environmental Defense Fund.

(*9*) Transcript of February 18, 1977 meeting between Commission staff and EDF representatives.

(*10*) Transcript of March 2, 1977 Commission meeting with Dr. Schneiderman, NCI.

(*11*) Transcript of March 8, 1977 Commission meeting with EDF representatives.

(*12*) February 1, 1977 petition (FP 77–1) from Ms. Joanne Seigel and Dr. Reuben Epstein.

(*13*) Transcript of Proceedings—National Institute of Health Meeting of Data Evaluation and Risk Assessment Subgroups of the Clearinghouse on Environmental Carcinogens—March 25, 1977.

(*14*) March 26, 1977 memorandum from R. M. Hehir to Michael Brown and attached meeting log.

(*15*) Final Report—Subchronic and Radioactive ^{14}C Tracer Studies of TRIS (2,3-dibromopropyl) phosphate in Laboratory Rodents, prepared by Bureau of Biomedical Science/CPSC, April 1, 1977.

(*16*) February 15, 1977 memorandum from Albert F. Esch, Medical Director, on extrapolation of risk from animals to humans.

(*17*) February 18, 1977 memorandum from Rita A. Orzel, Ph. D., of the Commission's Division of Human Toxicology and Pharmacology in OMD, same subject as 16 above.

(*18*) March 21, 1977 letter from Hooper and Ames on hazards of carcinogenicity and mutagenicity to humans through dermal absorption and ingestion of TRIS.

(*19*) June 2, 1976 National Cancer Advisory Board report.

(*20*) "TRIS (2,3-dibromopropyl) phosphate: Mutagenicity of a Widely Used Flame Retardant," Vol. 195, (pp. 76–78) Jan. 7, 1977, by Drs. Michael J. Prival, Elena C. McCoy, Bezalel Gutter and Herbert S. Rosenkranz.

(*21*) March 15, 1977 memorandum from Margaret Neily, BES entitled "Review of Literature on Availability of TBPP from Treated Fabrics."

(*22*) March 16, 1977 memo from BBS entitled "Chemical Availability of Tris (2,3-dibromopropyl) phosphate (TBPP) and Dermal and Oral Absorption Models for Three Possible Use Patterns".

(*23*) March 8, 1977 Harris report entitled "Estimating the Cancer Hazard to Children from Tris-treated Sleepwear."

(*24*) March 1977 Brown, Schneiderman, Chu paper entitled "Estimates of Human Lifetime Carcinogenic Risk from Exposure to Tris."

(*25*) March 17, 1977 Bayard to Hehir memo entitled "Preliminary Analysis of Tris Induced Human Lifetime Risk to Cancer."

(*26*) June 1976 BEP report on sleepwear entitled "Tris and Children's Sleepwear."

(*27*) February 25, 1977 memorandum of James Sharman, OEX, with attached marketing study.

(*28*) March 1, 1977 BEA report entitled "Availability of Garments Treated with TBPP."

(*29*) Preliminary environmental assessment of a TBPP ban prepared by BEA.

(*30*) April 5, 1977 letter to CEQ Acting General Counsel David Tunderman.

Statutory Findings

Section 2(f)(1)(A) of the Federal Hazardous Substances Act (15 U.S.C. 1261 (f)(1)(A)) defines "hazardous substance" as "any substance or mixture of substances which is toxic * * * if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Section 2(g) of the FHSA (15 U.S.C. 1261(g)) states that "[t]he term 'toxic' shall apply to any substance * * * which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."

Section 2(q)(1)(A) of the FHSA (15 U.S.C. 1261(q)(1)(A)) defines "banned hazardous substance" as "any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous

substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted." If a product is a banned hazardous substance, it is prohibited from interstate commerce by section 4 of the FHSA (15 U.S.C. 1263). Seizures of banned hazardous substances in interstate commerce are authorized by section 6 of the FHSA (15 U.S.C. 1265). Sections 5 and 8 (15 U.S.C. 1264 and 1267) authorize the Commission to seek injunctions or criminal penalties against persons who violate the prohibitions listed in section 4 of the FHSA.

Section 15 of the FHSA (15 U.S.C. 1274) requires the automatic repurchase of banned hazardous substances. Manufacturers (including importers for resale) must repurchase from their purchasers. Distributors must repurchase from their purchasers. Dealers who sold at retail must repurchase from any person who returns the items to them. In every case, a refund of the purchase price must be made in addition to the payment of certain expenses incurred in returning the item(s). However, a recently-issued Commission regulation permits replacement or repair of banned items instead of repurchase, at the option of the owner (16 CFR 1500.203). The Commission's other regulation concerning FHSA repurchase requires that retailers place signs in their establishments informing customers of the repurchase (see 16 CFR 1500.202).

The Commission finds that children's wearing apparel containing TRIS that is currently in interstate commerce or will be introduced into interstate commerce in the future is a banned hazardous substance according to these applicable provisions of the FHSA. In addition, any children's wearing apparel containing TRIS that has not been washed, even if it has already been sold, is also banned as hazardous. Such wearing apparel is toxic and presents a substantial risk of cancer as a result of its foreseeable absorption through the skin and ingestion by mouthing. It is also of course intended for use by children.

The Commission believes that children's wearing apparel containing TRIS that is already in the hands of consumers and has been washed does not present a substantial risk of personal injury or illness. After children's wearing apparel containing TRIS is bought, worn, and washed, the risk decreases. As noted above, a few washings remove as much as 95 percent of the TRIS that can be absorbed or ingested. In addition it would be relatively easy for consumers to be sure that their children's apparel is washed a few times before it is worn. In fact, the Commission assumes that most of the apparel that consumers now own has already been washed one or more times.

The Commission believes that the available test data and analyses support a withdrawal of TRIS-treated children's wearing apparel from commerce but not a recall of such apparel that has already been sold to consumers and washed by them. Children's wearing apparel containing TRIS that is in interstate commerce on April 8, 1977 or that is introduced into interstate commerce after that date is banned. Such unwashed, brand-new apparel presents a substantial risk and the Commission's interpretation prohibits the sale of such apparel to consumers.

In addition, the Commission believes that uncut fabric containing TRIS sold at retail, if consumers make it into wearing apparel, presents the same risk of illness as wearing apparel containing TRIS that is sold at retail. The scope of this interpretation accordingly includes such uncut fabric.

The Commission also believes that wearing apparel that is merely sewn with thread containing TRIS does not present a substantial risk of illness. The scope of the interpretation thus includes only wearing apparel made from fabric containing TRIS.

The Administrative Procedure Act imposes requirements on agencies for notice of proposed rulemaking, opportunity for public participation, and a delayed effective date (5 U.S.C. 553). However, these requirements are not applicable to interpretive rules or general statements of policy and are therefore not applicable to the interpretation announced in this document. Even if the rules were to be considered general rulemaking, the Commission for good cause finds that notice and public comment and a delayed effective date are contrary to the public interest because the statutory intent and structure of the FHSA is that children's articles that present a substantial risk of illness based on their toxicity must be banned without any delay. As the legislative history states, "[t]oys or other articles intended for use by children which bear or contain a hazardous substance are banned by the language of the bill itself * * *." (Senate Report No. 1551, 89th Cong., 2d Sess., page 2).

Commission Action on Petitions

The Commission has interpreted the section 2(g)(1)(A) banning provision of the FHSA to apply to children's wearing apparel containing TRIS. Although this is not a rulemaking action, it provides a remedy that satisfies a major portion of the EDF's February 1977 petition (HP 77-8). In fact, the EDF urged the Commission, in a February 16, 1977 letter that followed the submission of its petition, to utilize the section 2(g)(1)(A) provision. The Commission's action similarly supersedes a major portion of the EDF's March 1976 petition (HP 76-10) which requested precautionary labeling for wearing apparel containing TRIS in specified amounts. The Commission believes that little or no wearing apparel containing TRIS, other than children's wearing apparel, is currently in interstate commerce or would be introduced into interstate commerce in the future.

The petition from Ms. Siegel and Dr. Epstein (FP 77-1) requests regulatory action under the Flammable Fabrics Act to address the hazard presented by children's sleepwear in sizes 0-6X containing TRIS. The Commission believes that it has granted this petition by interpreting section 2(q)(1)(A) as banning children's wearing apparel containing TRIS.

Portions of the EDF's February 1977 petition make requests that concern the use of flame retardants other than TRIS in wearing apparel. Specifically, the petition asserts that tetrakis (hydroxymethyl) phosphonium chloride (THPC) and Pyroset TKP may be hazardous. In addition, the petition seeks the following labeling for wearing apparel for which industry has not investigated the health effects: "[T]he toxic properties of the flame retardant chemical(s) used in this product have not been evaluated."

Although the Commission does not currently know which chemicals, if any, are hazardous, a labeling requirement under section 27(e) of the CPSA is under consideration by the Commission. The Commission will consider this portion of the February 1977 EDF petition as a petition under the Administrative Procedure Act to initiate a proceeding for a section 27(e) rule.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(A), (g), (q)(1)(A) and 10(a), 74 Stat. 372, 374, as amended 80 Stat. 1305; 15 U.S.C. 1261(f)(1)(A), (g), (q)(1)(A), 1269(a)) and under authority vested in the Consumer Product Safety Commission by the Consumer Product Safety Act (sec. 30(a), 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission proposes to amend 16 CFR Part 1500.18 by adding a new subsection (d) as follows:

§ 1500.18 Banned toys and other banned articles intended for use by children.

* * * * *

(c) [Reserved]

(d) *Toys and other children's articles presenting toxicity hazards.* Under the authority of sections 2(f)(1)(A), 2(g), 2(q)(1)(A), and 10(a) of the act, the Commission has declared that the following articles are banned hazardous substances because they are toys or other articles intended for use by children that are hazardous substances, or bear or contain hazardous substances in such manner as to be susceptible of access by a child to whom they are entrusted, based on the fact that they may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children, because of their toxicity:

(1) Children's wearing apparel made from fabric which contains TRIS (2,3-dibromoprophyl) phosphate and which is in interstate commerce on April 8, 1977 or which is introduced into interstate commerce after that date or which has not yet been washed (even if it has been sold before that date); and

(2) Uncut fabric, intended for sale to consumers for use in children's wearing apparel, which contains TRIS (2,3-dibromoprophyl) phosphate and which is in interstate commerce on April 8, 1977 or which is introduced into interstate commerce after that date or which has not yet been washed (even if it has been sold before that date).

Dated: April 7, 1977.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

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